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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,354	03/13/2001	M. Amin Arnaout	00786-536001	1935

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FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
HADDAD, MAHER M	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/805,354	ARNAOUT ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/04/02, 4/10/02 &* 1/6/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 46-50 are pending.

2. Applicant's election without traverse of Group II, claims 14, 16, 30, 32, 34, 36, 38, 40 and 42 (now claims 46-50) drawn to a polypeptide comprising amino acids 144-332 of full-length human CD11 alpha subunit and the mutation at amino acid 332 position as the species filed on 10/8/04, is acknowledged.

3. Claims 46-50 are under examination as they read on a polypeptide comprising amino acids 144-332 of full-length human CD11 alpha subunit and the mutation at amino acid 332 position.

4. Applicant's IDS, filed 3/04/02, 4/10/02 and 01/06/03, is acknowledged.

5. The amendment filed 2/15/02, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The preliminary amendment filed on 2/15/02 to the to FIG.2A of the drawings substituting original Fig.2A with a new FIG.2A represents a departure from the specification and the claims as originally filed. The new electron density map of the C-terminal portions of α7 from $11bA^{123-321}$ structure is different than the originally filled electron density map. The specification and the claims as originally filed have no support for the new replacement of electron density map of the C-terminal portions of α7 from $11bA^{123-321}$ structure.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 46-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 46 is indefinite and ambiguous in the recitation of "amino acids 144-332 of full-length human CD11a wherein the Ile at amino acid 332 has been replaced" in lines 1-2. Recitation of amino acid position of a protein without providing SEQ ID NO for the protein is indefinite and ambiguous because different laboratories may have different numbering of the same protein. It is unclear whether amino acids refer to mature or immature CD11b. It is unclear whether the CD11b is a 187, 191, 1152, 1153 amino acid sequence.

B. Claim 47 is indefinite and ambiguous. Claim 47 depends form claim 46, which recites modified human CD11 (i.e., wherein the Ile at amino acid 332 has been replaced", claim 47 recites unmodified human CD11b (i.e., the entirety of full-length human CD11b). Claim 47 now recites unmodified human CD11b.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 50 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The phrase "wherein the Ile at amino acid 189 is replaced by an amino acid other than Ile" claimed in claim 50, lines 2-3 represents a departure from the specification and the claims as originally filed.

Applicant's amendment filed 10/8/04 does not point to the specification for support for the newly added limitation "wherein the Ile at amino acid 189 is replaced by an amino acid other than Ile" as claimed in claim 50. However, the specification does not provide a clear support of "wherein the Ile at amino acid 189 is replaced by an amino acid other than Ile". It is noted that SEQ ID NO: 1 is the A domain C144-334 of full-length human CD11b of GenBank Accession No. RWHU1B. The instant claim now recites a limitation which was not clearly disclosed in the specification and recited in the claims as originally filed.

10. Claims 46-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not reasonably provide enablement for a purified polypeptide comprising amino acids 144 to 332 of full length human CD11b wherein the Ile at amino acid 332 has been replaced by an amino acid other than Ile in claim 46, which comprising the entirety of Full-length human CD11b in claim 47, wherein the Ile at amino acid 332 is replaced by a Gly in claim 48 or Ala in claim 49, the polypeptide comprising amino acids 1-191 of SEQ ID NO:1 wherein the Ile at amino acid 189 is replaced by an amino acid other than Ile in claim 50. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There is insufficient guidance and direction as to make and use the full length human CD11b, wherein the specification fails to provide a structure for the human CD11b.

It is unclear form the specification as to the relationship between amino acid numbering of Ile^{316} and Ile^{332}. The specification on page 7, discloses that Table 2 and 3 refer to the numbering in the complete protein (including 16 aa signal sequence). It appears that Ile^{316} corresponds to the incomplete human CD11b and the Ile^{332} corresponds to the complete human CD11b subunit. Therefore, it appears that Ile^{316} and Ile^{332} are the same amino acid residue of the human CD11b.

Applicant has not provided sufficient biochemical information (e.g. molecular weight, amino acid composition, N-terminal sequence, etc.) that distinctly identifies such human CD11b other than the GenBank accession number RWHU1B improperly incorporated by reference (page 14, table 2). Claiming biochemical molecules, human CD11b, by properties fails to provide sufficient guidance and direction as to how the skilled artisan can make and use such "human CD11b", commensurate in scope with the claimed invention. It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions can result in substantially different biological activities. Applicant has not enabled structurally related and unrelated compounds comprising "amino acids 144 to 332" or "SEQ ID NO:1" which would be expected to have greater differences in their biological activities. There is insufficient direction or objective evidence as to how to make and to how to use human CD11b, and in turn how to obtain the Ile^{332} variant thereof. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

Further, it is apparent that the amino acid sequence disclosed in GenBank Accession No. RWHU1B, disclosed on page 14, Table 2, 2nd row is required for making and using the claimed invention. However, Applicant has not provided the sequence. The amino acid sequence is considered essential subject matter to the instant application and the claimed invention.

The incorporation of essential material in the specification by reference to GenBank Accession No. RWHU1B is improper. An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973

The attempt to incorporate subject matter into this application by reference to GenBank Accession No. RWHU1B is improper because an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, see MPEP 608.01(p),. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or

application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

11. Claims 46-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of a purified polypeptide comprising amino acids 144 to 332 of full length human CD11b wherein the Ile at amino acid 332 has been replaced by an amino acid other than Ile in claim 46, which comprising the entirety of Full-length human CD11b in claim 47, wherein the Ile at amino acid 332 is replaced by a Gly in claim 48 or Ala in claim 49, the polypeptide comprising amino acids 1-191 of SEQ ID NO:1 wherein the Ile at amino acid 189 is replaced by an amino acid other than Ile in claim 50.

Neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms, that are common to the genus. That is, the specification provides neither a representative number of species (human CD11b) to describe the claimed genus, nor does it provide a description of structural features that are common to species (CD11b). As discussed above, the specification provides no structural description of CD11b other than the one disclosed in GenBank Accession No. RWHU1B; in essence, the specification simply directs those skilled in the art to go figure out for themselves what the claimed human CD11b looks like. The specification's disclosure is inadequate to describe the claimed human CD11b.

Applicant has disclosed only the amino acids of GenBank Accession No. RWHU1B (improperly incorporated by reference); therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or

by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 47 is rejected under 35 U.S.C. 102(b) as being anticipated by Corbi *et al* (1988).

Corbi *et al* teach the entirety of full-length human CD11b (see Fig. 2, page 12406 in particular).

The reference teachings anticipate the claimed invention.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
November 23, 2004

Christina Chan

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600